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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,555	01/16/2004	Robert Jiang	03-185	8126
27716	7590	07/06/2005	EXAMINER	
CV THERAPEUTICS, INC. 3172 PORTER DRIVE PALO ALTO, CA 94304			OWENS, AMELIA A	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/759,555	<b>Applicant(s)</b> JIANG ET AL.	
	<b>Examiner</b> Amelia A. Owens	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 12, 14, 16, 18, 20, 25, 27 and 29-33 is/are rejected.
- 7) ☒ Claim(s) 2-9, 11, 13, 15, 17, 19, 21-24, 26, 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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The specification does not recite starting materials to make compounds where V is CH= or NHCH=. The starting materials are necessary to prepare compounds as set forth in the claims. Further, it is not clear if the same reaction mechanism, reaction conditions would produce compounds where V is CH or NHCH. The specification at pages 20-32 is directed solely to compounds where V is nitrogen.

Claims 2-9,11,13,15,17,19,21-24,26,28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Allowable Subject Matter*

The prior art neither teaches nor suggests the claimed compounds or methods for using them. See for example, Fan et al (CA 108:5971); Berthold et al (CA 105:172505) that teach compounds similar to the invention. The prior art compounds teach Y-X1 being monocyclic heterarylenyl that is hydrogen *substituted only*. In the present claims the corresponding Y-X1 is *dihydroheteroaryl* (one double bond remains unsaturated) that may be optionally substituted.

It is known in the pharmaceutical arts to treat damage to skeletal muscles resulting from trauma, shock, and cardiovascular disease (wherein the cardiovascular disease is atrial arrhythmia, intermittent claudication, ventricular arrhythmia, Prinzmetal's (variant) angina, stable angina, exercise induced angina, congestive heart disease, or myocardial infarction) with the same compound. See Blackburn et al (WO 01/62749 A1) abstract.

Copending applications 10/198237, 10/346684, 10/759562 teach compounds similar to those claimed, i.e. Y is heteroaryl optionally substituted. However, for the present claims Y

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**DETAILED ACTION**

Claims 1-33 are pending. No drawings were filed. Foreign priority was not claimed.

***Information Disclosure Statement***

The examiner has considered the IDS.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 recites the limitation "wherein the disease state is diabetes". There is insufficient antecedent basis for this limitation in the claim. Note claim 31 from which claim 32 depends is limited to ---cardiovascular diseases----. It is suggested the claim depend from claim 30 that recites 'diabetes'.

Claims 10, 12, 14, 16, 18, 20, 25, 27, 29 recite the limitation "an isomer of the compound..." in the preamble. There is insufficient antecedent basis for this limitation in the claim. Note the claims depend indirectly from claim 1 which does not recite 'isomers' of the claimed compound.

It is noted that page 16 of the specification refers to isomers.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

*1 and 30-33*

Claims ~~1-33~~ are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being *enabling for V being nitrogen*, does not reasonably provide enablement for *V being CH= or NHCH=*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

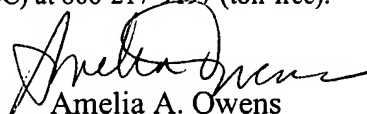
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must be *dihydroheteroaryl* (one double bond remains unsaturated). Thus, there is no double patenting issue as the claims are not directed to the same inventive concept.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Amelia A. Owens  
Primary Examiner  
Art Unit 1625